K003110

DEC - 1 2000

510(k) SUMMARY

A. Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 (215) 256-4201 Telephone (215) 256-1787 Fax
Contact:	Florence A. Caikoski
Date Prepared:	October 2, 2000

B. Trade Name: Medcomp Bio-Cath Catheter Line
Common Name: Intravascular Catheter, Long-term
Classification: LJS
C.F.R. Section: 880.5200

C. Predicate Device: K841587 Gish Central Vein Access Catheter

D. Device Description:

The Medcomp Bio-Cath product line is intended to provide central vein access. The single lumen versions are offered in 6F, 7F and 9.5F outer dimensions, and 7F, 9.5F, 11F and 14Fdouble lumen versions. All versions are 90cm long. The catheters are manufactured from soft, radiopaque silicone that conforms well to vessel anatomy.

E. Intended Use:

The Medcomp Bio-Cath™ Central Venous Catheter is designed for Long-Term central venous access in adults and children. It can be used for total parenteral nutrition (T.P.N.), infusion of I.V. liquids, blood, blood products, and drugs. It can also be used for repeated withdrawal of blood samples.

It is inserted percutaneously and is primarily placed in the subclavian vein with tip ending in mid to lower SVC. Alternate insertion sites include internal jugular as required.

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F. Comparison to Predicate Device:

The technological characteristics of the Bio-Cath Catheters substantially equivalent to the predicate in terms of intended use, insertion method, anatomical location, patient population, design, materials and performance characteristics.

G. Performance Data:

In Vitro performance data for the Medcomp Bio-Cath Catheter line, including tensile strength, joint strength, air leakage, liquid leakage and flow performance demonstrate that this device is substantially equivalent to legally marketed devices intended for infusion treatments.

Biocompatibility testing on the Bio-Cath demonstrates the materials used meet the requirements of ISO 10993 for a permanent contact device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 1 2000

Ms. Florence A. Caikoski
Regulatory Affairs Associate
Medcomp
1499 Delp Drive
Harleysville, Pennsylvania 19438

Re: K003110
Trade Name: Bio-Cath™ Central Venous Access Catheter
Regulatory Class: II
Product Code: LJS
Dated: October 2, 2000
Received: October 4, 2000

Dear Ms. Caikoski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

this letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Runres for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K 003110

Device Name: Bio-Cath™ Central Venous Access Catheter

Indications for use:

The Medcomp Bio-Cath™ Central Venous Catheter is designed for Long-Term central venous access in adults and children. It can be used for total parenteral nutrition (T.P.N.), infusion of I.V. liquids, blood, blood products, and drugs. It can also be used for repeated withdrawal of blood samples.

It is inserted percutaneously and is primarily placed in the subclavian vein with tip ending in mid to lower SVC.

Alternate insertion sites include internal jugular as required.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003110